

Generic Information Collection: Emerging mosquito-borne diseases: assessment of chikungunya and dengue-related knowledge, attitudes and practices for Mexican-origin audiences along the U.S-Mexico border

Generic Information Collection Request

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Statement A

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- The goal of this project is to describe Mexican-born border residents' knowledge, attitudes, and practices about chikungunya and dengue, and evaluate existing educational materials in Spanish for cultural and linguistic appropriateness.
- The results will be used to improve the cultural and linguistic appropriateness of CDC's chikungunya and dengue materials for border residents.
- Up to 10 focus groups will be conducted with members of the population of interest.
- The population of interest is adult Mexican-born U.S.-Mexico border residents.
- Data will be analyzed using qualitative thematic analysis using software such as NVivo, AtlasTI, or MAXQDA.

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), received approval of a new “generic clearance” to facilitate the implementation of qualitative data collection projects to help us to better understand the knowledge, attitudes and practices related to communicable and other emerging diseases among foreign-born individuals in limited, targeted geographic areas of the United States, e.g. neighborhoods, cities, and counties. Foreign-born individuals include temporary and permanent immigrants, international visitors, and refugees settled in the United States.

The information collection is in accordance with DGMQ's mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. This mission is supported by delegated legal authorities

Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries or possessions into the United States and from one state or possession into any other state or possession. These regulations are codified in 42 Code of Federal Regulations (CFR) Parts 70 and 71 (Attachments C and D).

The Secretary of Health and Human Services also has the legal authority to establish regulations outlining the requirements for the medical examination of aliens before they may be admitted into the United States. This authority is provided under the Immigration and Nationality Act (8 U.S.C. § 1182(a) (1)(A)) (Attachment E) and Public Health Service Act (42 U.S.C § 252)(Attachment F). These regulations are codified in 42 CFR Part 34 (Attachment G), which establish requirements that determine whether aliens can be admitted into the United States.

CDC is also authorized to do Research and investigations generally and to collect these data under the Public Health Service Act (42 USC 241), Section 301 (Attachment H)

Foreign-born populations pose risks for introduction of communicable and emerging diseases into and/or within the United States and are vulnerable to higher morbidity and mortality because of international disease exposures, language, legal and cultural barriers and limited access to preventive care and health information once settled in the United States.

This qualitative data collection is needed by DGMQ because foreign-born individuals are considered hard-to-reach populations and are often missed by routine information collection systems in the United States [1-3]. As a consequence, limited information is available about the health status [4], knowledge, attitudes, health beliefs [5-7] and practices related to communicable diseases and other emerging health issues (e.g., tuberculosis, influenza, viral hepatitis, rickettsial and parasitic diseases) amongst foreign-born populations in the United States [8]. Foreign-born populations are very diverse in terms of countries of origin, socio-demographic, cultural and linguistic characteristics and geographic destinations in the U.S. Data is especially limited at the local level.

Since its first appearance in the Western Hemisphere in December 2013, over 1.3 million cases of chikungunya virus have been reported in the Americas, with outbreaks encompassing 44 countries and territories throughout the Caribbean, South America, Central America, and now several states in northern Mexico. Based on our experience with dengue, which is transmitted by the same mosquito species, the arrival of chikungunya along the United States-Mexico border is imminent. The risk is greatest in areas with established populations of mosquito vectors and large numbers of travelers arriving from chikungunya or dengue-outbreak areas. Outbreaks have been reported throughout Mexico and, in particular, in Mexican states bordering the United States.

Unlike the sweeping outbreaks currently occurring in more tropical climates, CDC anticipates that sporadic and local chikungunya outbreaks within the continental United States will occur in border states. It is only a matter of time before local transmission of chikungunya occurs along the U.S.-Mexico border (Arizona, California, New Mexico, and Texas). In order to facilitate early recognition of cases and/or outbreaks along the U.S.-Mexico border, CDC recommends that state health agencies in high risk border states should immediately expand activities to inform key target audiences about chikungunya risk, identification and prevention. Though our campaign seeks to educate this region about chikungunya, a new emerging mosquito-borne disease, sporadic outbreaks of dengue have also occurred in this region and education efforts will also incorporate joint chikungunya-dengue awareness and prevention.

There are more than 7 million Mexican-born residents in the four U.S-Mexico border states. This population is culturally unique; many of them speak Spanish as their primary language and have limited proficiency in English, and have different communication needs, media preferences, and healthcare seeking behaviors from the general U.S. audience and other border residents. Many of them cross frequently between the United States and Mexico to work, go to school, visit family, and shop. Social contacts and sharing of health information and risks thus occurs in a single binational epidemiologic environment, which must be understood as such.

In preparation for chikungunya and dengue outbreak in the U.S.-Mexico border region, it is necessary to develop culturally and linguistically appropriate educational materials in Spanish that will meet the information and education needs of the Mexican-born resident population and will help prevent and manage the spread of chikungunya in the border region. We need to better understand the messaging

preferences and the current state of knowledge, attitudes and practices (KAP) of this population to provide an effective and targeted chikungunya and dengue awareness campaign. Funding a campaign like this can more effectively educate the Mexican-born border population about the emergence of chikungunya and dengue, symptoms and effects, and how families can protect themselves, their loved ones and by extension their communities.

Federal, state (California, Florida, Arizona, Texas, and New Mexico) and local partners have already begun a collaboration to address this challenge. A Chikungunya Border Workgroup consisting of federal, state and local partners is working to define health education needs and to design and produce bilingual materials such as PSAs, posters, HANs, and a media toolkit.

In order to make these tools maximally effective, it is imperative to culturally and linguistically validate messages and educational materials being developed for the border population, by conducting formative evaluation of those materials with the Mexican-born population in the U.S Mexico-border region.

2. Purpose and Use of the Information Collection

The two main purposes for this data collection are:

- 1) Describe Mexican-born border residents' knowledge attitudes and practices about chikungunya and dengue, including transmission, symptoms, treatment, and prevention measures.
- 2) Evaluate existing and draft chikungunya and dengue materials in Spanish for cultural and linguistic appropriateness.

Findings from this project will help inform a U.S.-Mexico chikungunya and dengue education campaign for Spanish-speaking Mexican-born populations CDC plans to conduct in 2015.

3. Use of Improved Information Technology and Burden Reduction

To the extent possible, project officers have tried to minimize the generation of hard copy forms and responses necessary to conduct this information collection. Responses from participants will be recorded using an audio recording device one time only, when the focus groups take place. This will reduce the burden and ease of the submission of information to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

A review of the scientific and gray literature indicates that no other agency is collecting similar data on culturally and linguistically appropriate messaging and educational materials for this particular foreign born population concerning chikungunya and dengue.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection. Respondents are primarily temporary and permanent immigrants from Mexico living in the United States border region.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time data collection. There are no legal obstacles to reduce the burden. Given the likely possibility of chikungunya introduction into the United States, CDC and other public health partners need to better understand the messaging preferences and the current state of knowledge, attitudes and practices of this population to provide an effective and targeted chikungunya and dengue awareness campaign. Early and targeted development of appropriate health messaging can more effectively educate the Mexican-born border population in the United States about the emergence of chikungunya and dengue, symptoms and effects, and how families can protect themselves, their loved ones and by extension their communities. This information will help reduce the burden of disease in the border region and throughout the entire country.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information. This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A notice detailing the proposed data collection activities was published in the Federal Register on, Wednesday, May 14, 2014, Vol. 79, PP 27618- 27619. (Attachment B). No comments were received.

B. CDC did not consult with outside persons on the development of these forms. The forms represent data that is already captured by state and local health departments and maritime operators. CDC collects these data on a voluntary basis. The forms are tools to facilitate transfer of this information to CDC. However, CDC has collaborated with federal, state (California, Florida, Arizona, Texas, and New Mexico) and local partners to define health education needs and to design and produce bilingual materials such as PSAs, posters, HANs, and a media toolkit.

9. Explanation of Any Payment or Gift to Respondents

DGMQ will not directly offer cash incentives to the participants targeted in this information collection. However, the organization contracted to conduct recruitment will provide small, tangible tokens of appreciation for participants' time. Given that the target population is expected to be of low socioeconomic status and may have limited access to transportation, a small cash stipend (\$20 to \$40) or other non-monetary incentive for the same value (e.g., a transportation voucher, phone cards, gift cards) will be offered to the focus group participants as a token of appreciation for a respondent's time and interest in the project and to reimburse for expenses such as transportation and childcare costs. Incentives will be provided upon completion of focus group participation.

Incorporating modest incentives (e.g., between \$20 and \$40) or non-monetary incentives to aid in recruitment for focus groups is standard practice among commercial market researchers and public health researchers. The level of incentive payment will be determined after consulting with community

representatives, community-based organizations and trained focus group moderators who have worked with similar populations in the past. CDC will attempt, through participation with local partners and location of focus group facilities, to limit inconveniences associated with travel.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases who has determined that the Privacy Act does not apply. As noted above, all focus group discussion participants will be informed that discussions are private. As such, no identifiers (other than audio recording) will be used. First names may be written during the course of discussion, however, no last names or other identifiers will be recorded. Participants are free to use a pseudonym if they would like to have a greater degree of assurance about privacy. Further, any information communicated by participants will not be associated with any particular individual's name in any reports or other materials, and no System of Records is being created. DGMQ, contractors, and partner organizations will follow procedures for securing and maintaining privacy during all stages of information collection. Participants will be recruited directly by CBOs. Partner organizations and contractors will collect and analyze the project specific data. DGMQ will provide technical assistance in the design, implementation, and analysis of the project but will not have contact with project participants (and will only have access to coded, de-identified data). All information provided by participants will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Participants will be informed prior to participation that their responses will be treated in a secure manner.

Project proposal (Attachment N) was reviewed by CDC and determined to be non-research on June 26 (See Attachment O).

10.1 Privacy Impact Assessment Information

1. Overview of the Data Collection System – The data collection system to be used consists of a Focus Group Discussion Guide (Attachment I) for up to 10 focus groups with members of the Mexican-born population in border communities in the following four states: Texas, Arizona, New Mexico and California. Each focus group will include up to 12 adult members of the target population. The focus groups, which will be conducted in Spanish, are designed to assess participants' knowledge, attitudes and practices regarding vector borne disease transmission, mosquito prevention, and message testing for chikungunya using the attached materials. The data collection instruments will be administered in person.

Potential participants will be screened and selected based on age, nationality, preferred language. If the individual is under 18, the screening will end (Attachment J). Further questions include, but are not limited to, demographic information concerning where the potential participant lives in relation to the border and how long they have lived there (Attachment K).

2. Description of the Information to be Collected – The screening form will collect basic demographic information to determine the individuals eligibility (adult, foreign born) residence in the U.S.-Mexico border region. The focus group discussion will ask participants a series of

questions to assess participants' knowledge, attitudes and practices regarding vector borne disease transmission, mosquito prevention, and message testing for chikungunya using the attached materials.

3. A description of how the information will be shared and for what purpose – Results of this data collection will be used to review, edit existing messages and materials and develop prevention messages and educational materials on dengue and Chikungunya in the U.S.-Mexico Border Region. Findings will be presented at national and international conferences about health communications and U.S.-Mexico border health issues, as well as with other CDC and border health partners, including the state, local, and the intergovernmental Chikungunya Border Workgroup (Attachments L and M).
4. A statement detailing the impact the proposed collection will have on the respondent's privacy - No personally identifiable information (PII) will be collected during this project. The proposed data collection will have little or no effect on the respondent's privacy. All data will always be reported in an anonymous manner. Participants will not be able to be identified either directly or indirectly from the information that appears in the final data set.
5. Whether individuals are informed that providing the information is voluntary or mandatory – Individuals are informed that participation is voluntary both during screening for eligibility and when provided the information sheet immediately prior to participation in the focus group. Individuals are informed that participation is voluntary and they may leave at any time, either prior to or during the focus group.
6. Opportunities to consent, if any, to sharing and submission of information - All potential participants will receive the participant information sheet outlining the basic details of the focus group. Included in this sheet is the following statement to ensure participants that they cannot be identified after the focus group. If this statement is not sufficient for the participants to feel comfortable about their de-identified answers being shared, they are free not to participate.
 - a. “None of the information being collected is of a personal nature. We will protect this information to the extent allowed by law. We will not keep a written record of your name, and the information you share will not be used in any report so that you can be identified. By agreeing to participate, you agree to let us audio record today's discussion. We will destroy the audio recording after 3 years. While we ask that the other participants do not talk about what we discuss today outside of the group, there is the possibility that they might talk and so we cannot guarantee complete privacy in this case.”
7. How the information will be secured - All data will be stored in secured electronic files at CDC's and/or a contractor's office and will be accessible only to staff directly involved in the project. All members of the project will be required to sign a statement pledging their personal commitment to guard the security of data. Data files will be retained for a period of no more than three years and then destroyed. After the three years, the documents and multimedia recordings

will be deleted. Online data collections will conform totally to federal regulations [the Hawkins-Stafford Amendments of 1988 (P.L. 100-297) and the Computer Security Act of 1987] and will be required to have comprehensive, written plans to maintain security. This plan will include having all personnel who will have access to individual identifiers sign data security agreements. They will also be trained in the meaning of data security, particularly as it relates to handling requests for information from respondents, and in providing assurance to respondents about the protection of their responses.

8. Whether a system of records is being created under the Privacy Act – No System of Records will be created as a part of this project. No PII will be stored from focus group participants in group sessions.

11. Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. However, some respondents may find thinking about and discussing a disease unpleasant, or a portion of respondents could consider questions about race, ethnicity, or other demographic characteristics to be sensitive. Where relevant to the information collection, race and ethnicity data will be collected consistent with HHS policy and standard OMB classifications.

Additionally, some respondents may feel uncomfortable answering particular questions about their individual experiences, level of disease awareness, beliefs and/or adopted preventative behaviors (or lack thereof) associated with various diseases. However, such questions are necessary for the purposes of a targeted CDC activity and thus to the information collection. To minimize psychological distress, the interviewer or focus group moderator will inform participants that they do not have to respond to any questions they do not want to answer and they may stop participating at any time. Each individual information collection will provide justification for the inclusion of any questions that may be of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

A. DGMQ estimates that 240 Mexican-born people living in the U.S.-Mexico border region will be screened using the Participant Screener form; of those, only 120 will be eligible to participate and recruited for information collection activities each year. 240 individuals will be screened once, with a burden of 10 minutes per screening, for a total burden of 40 hours. It is estimated that there will be up to 10 focus groups, with 12 participants per focus group.

Table A.12-A: Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Mexican-born living in the U.S-Mexico border region	Participant Screener	240 (240 people screened, 120 of those eligible to participate in focus groups)	1	10/60	40
Mexican-born living in the U.S-Mexico border region	Focus Group Discussion Guide	120 (Up to 10 focus groups and up to 12 participants per focus group)	1	120/60	240
Total estimated annualized burden hours to respondents					280

It is estimated that information collection activities will total 280 burden hours per year, at an annualized cost to respondents of \$6,358.80.

Table A. 12-B: Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Mexican-born living in the U.S-Mexico border region	Participant Screener	40	\$22.71	\$908.40
Mexican-born living in the U.S-Mexico border region	Focus Group Discussion Guide	240	\$22.71	\$ 5,450.40
Total estimated annualized cost to respondents				\$6,358.80

*Public wages from http://www.bls.gov/oes/current/oes_nat.htm#00-0000

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time.

14. Cost to the Federal Government

The cost to the federal government for the proposed information collection activities is \$149,920. This figure encompasses 2% FTE of two GS-13 employees and information collection contract costs. The average hourly rate was obtained from the Office of Personnel Management’s website (<http://www.opm.gov/oca/09tables/html/atlh.asp>). The hourly rate for a GS-13 in the San Diego area is \$42.65 per hour, which is about \$89,000 per year. The contractual cost for an information collection (e.g. the development of a screener and instrument, participant recruitment, incentive payments, facility rental (when applicable), transcriptions, translation services and final reports) is estimated at \$149,920.

Table A.13: Estimated Annualized Cost to the Government per Activity and Total

Cost Category	Estimated Annualized Cost
Federal employee costs for information collection (2% FTE of two GS-13 at \$89,000/year)	\$7,120
Contractual costs for an information collection: a) Focus groups (e.g. facility rental, moderator, participant recruitment, translations, transcriptions, incentive payments and final reports)	(10 focus groups @\$14,280) = 142,800
Total cost of information collections/year	\$149,920

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Subject to contingencies outside the control of the CDC project team, the Plans for Tabulation and Publication and Project Time Schedule are as follows:

- **July 2015:** Initiate OMB process and seek IRB exemption
- **August 2015:** Partner local health departments and community based organizations recruit focus group participants
- **September 2015:** Conduct focus groups
- **October-December 2015:** Analyze data
- **February 2016:** Finalize project report

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate, CDC request no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

List of Attachments

Attachment A - 42 USC 264
Attachment B – 60 day Federal Register Notice
Attachment C - 42 CFR Part 70
Attachment D - 42 CFR Part 71
Attachment E - 8 U.S.C. § 1182(a)(1)(A)
Attachment F - 42 U.S.C § 252
Attachment G - 42 CFR Part 34
Attachment H: 42 U.S.C. § 241
Attachment I: Focus Group Discussion Guide
Attachment J: Participant Screener
Attachment K: Participant Information Sheet
Attachment L: Chikungunya and Dengue Messages
Attachment M:
Attachment N: IRB Research Protocol
Attachment O: IRB Non-Research Determination

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